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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,711

06/26/2003

Stephen D. Pacetti

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7590

03/11/2008

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EXAMINER

AHMED, SHEEBA

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/606,711	Applicant(s) PACETTI, STEPHEN D.	
	Examiner SHEEBA AHMED	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-20, and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 31, 2008 has been entered.

Response to Amendments

2. Amendments to claims 1, 12, and 22 have been entered in the above-identified application. Claims 11 and 21 are cancelled. **Claims 1-10, 12-20, and 22-29 are now pending.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-10, 12-20, and 22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. (US 6,926,919 B1).

Hossainy et al. disclose a coating for an implantable medical device wherein the coating comprises a hydrophobic and hydrophilic component (Column 2, lines 35-40). The mass ratio between the hydrophilic and hydrophobic polymers in the coating can be typically between about 1:100 and 1:9 (Column 3, lines 16-21). A specific embodiment discloses drug eluting vascular stents having a coating including a blend of a hydrophobic and hydrophilic polymer and treating the coating with a stimulus for enriching a region close to the outer surface of the coating with a hydrophilic polymer such that the region of the coating close to the outermost surface of the stent has a higher content of the hydrophilic component than the hydrophobic component (Column 2, lines 12-40). The coating further comprises an optional primer layer and an optional topcoat layer (Column 2, lines 42-60). Poly(ethylene-co-vinyl alcohol) is one example and it can be used to fabricate the topcoat or primer layers as well. Other examples include the list given in Columns 3 and 4. Following the formation of the outermost layer of the stent coating comprising a blend of hydrophobic and hydrophilic polymer(s), the surface of the coating can be treated to enrich the surface with hydrophilic polymer(s). In order to enrich the surface with hydrophilic polymer(s), various methods of treatment of the stent coating can be used. According to one method of the post-coating treatment, the coated stent can be exposed to the environment of a humidifying chamber. As a result of the exposure of the stent to high humidity levels at elevated temperatures, water is expected to be

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deposited on the surface of the stent coating. Water will gradually extract the hydrophilic polymer to the coating surface leading to migration of the hydrophilic polymer and its blooming to the coating-air interface **(hence inherently leading to a second layer of a hydrophilic polymer on top of the outermost layer having the blend of the hydrophobic and hydrophilic polymer)**. According to another method of the post-coating treatment, the coated stent can be physically placed on a film of a hydrogel, for example, a poly(vinyl alcohol) hydrogel, and gently rolled back and forth a number of times covering the entire circumference of the stent. For example, the coated stent can be rolled in the described fashion between 5 and 10 times, while a pressure of between about 1 atm and 3 atm is applied to the stent when it is being rolled. The physical contact between the film of the hydrogel and the stent coating can alter the coating-air interface, resulting in extraction of the hydrophilic polymer and its blooming to the coating-air interface. The above procedures are expected to lead to extraction of the hydrophilic polymer and its blooming to the coating-air interface. All limitations of claims 1-10, 12-20, and 22-29 are recited in the above reference.

Response to Arguments

4. Applicant's arguments filed on January 31, 2008 have been fully considered but they are not persuasive. Applicants traverse the rejection of the claims under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. (US 6,926,919 B1) and submit that the instant claims define a method for fabricating a coating for an

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implantable medical device wherein the method comprises (a) forming a first layer of the coating on the device, and (b) forming a second layer of the coating on at least a portion of the first layer whereas Hossainy, the Applicants assert, has no description of coating that includes a second layer over the first layer wherein the second layer being water soluble.

However, the Examiner disagrees. Hossainy et al. disclose a coating for an implantable medical device wherein the coating comprises a hydrophobic and hydrophilic component and in a specific embodiment the coating includes a blend of a hydrophobic and hydrophilic polymer and is treated with a stimulus for enriching a region close to the outer surface of the coating with a hydrophilic polymer such that the region of the coating close to the outermost surface of the stent has a higher content of the hydrophilic component than the hydrophobic component (Column 2, lines 12-40). In fact, Hossainy specifically states that following the formation of the outermost layer of the stent coating comprising a blend of hydrophobic and hydrophilic polymer(s), the surface of the coating can be treated to enrich the surface with hydrophilic polymer(s) such that the hydrophilic polymer is extracted to the coating surface leading to migration of the hydrophilic polymer and its blooming to the coating-air interface. Hence, the Examiner is taking the position that the above-described post-treatment of the outermost layer inherently leads to the formation of a second layer comprised of a hydrophilic polymer which would inherently be water-soluble.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEEBA AHMED whose telephone number is (571)272-1504. The examiner can normally be reached on Monday-Friday from 8am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheeba Ahmed/
Primary Examiner, Art Unit 1794
February 29, 2008